US-PAT-NO: 6425877

DOCUMENT-IDENTIFIER: US 6425877 B1

TITLE: Treatment of tissue in the digestive circulatory respiratory urinary and reproductive systems

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Brief Summary Text - BSTX (5):

The circulatory, respiratory, urinary, reproductive and digestive systems of human beings, livestock and other mammals are subject to a number of disorders and diseases. Disorders in the circulatory system include aneurysms of the aortic arch, thoracic aorta and abdominal aorta. Disorders in the respiratory system include occlusion of the trachea and tumors and **polyps** in the hypopharynx, oropharynx, nasopharnyx and larynx. Disorders in the urinary system include incontinence and urinary neuropathy. Disorders of the reproductive system include obstruction of the vas deferens, obstruction of the fallopian tubes, uterine cysts and fibroids, prolapsed uterus, menorrhagia and tumors or cancerous tissue. Disorders in the digestive system include Barrett's esophagus, occlusion of the bile ducts, occlusion of the pancreatic ducts, tumors and cancerous tissue found in the stomach and related structures. Other disorders in the rectum and colon include hemorrhoids (external and internal), fecal incontinence, prolapsed rectal muscles, rectal muscle spasms, anal fissures, **polyps,** diverticulosus, diverticulitus and pilonital cysts.

Detailed Description Text - DETX (7):

The inflatable microporous **balloon** 120 includes multiple arrays of regularly positioned electrodes 121 embedded into the wall of the **balloon**. Each electrode 128 includes a metallic **tube** 122 defining a hollow lumen 123, a temperature sensor 124 an impedance sensor 125 and a sensor for measuring nervous activity. In addition to ablating tissue by delivering RF energy, the electrodes are disposed to deliver at least one flowable substance to the area where ablation is to take place. In a preferred embodiment, the flowable substance includes saline with a concentration of less than about 10% NaCl, which aids in hydration of body structures. However, in alternative embodiments, the deliverable, flowable liquids include other substances, including anesthetic drugs, anti-inflammatory agents, chemotherapeutic agents, systemic or topical antibiotics, collagen and radioactive substances such as labeled traces. In alternative embodiments, the overall dimensions of the inflatable microporous **balloon** 120 can vary as long as they are responsive to the dimensions of the targeted tissue. For instance, the dimensions of an inflatable, microporous **balloon** 120 that is used to ablate tissue in a uterus will be larger than those of an inflatable microporous **balloon** that is used to ablate tissue in a fallopian **tube**. In other alternative embodiments, the shape and length of the electrodes may vary.

Detailed Description Text - DETX (10):

The port 131 can be coupled to a source of RF energy. The port 132 can be coupled to visualization apparatus, such as fiber optic devices, fluoroscopy equipment and related **endoscopic** apparatus, to allow internal viewing of the targeted tissue. The female coupling 133 can be connected to a syringe or other dive to which positive pressure can be applied to inflate the balloon 120. In a preferred embodiment, female coupling 134 can be connected to biologically nonreactive tubing through which saline can be infused so that the saline can continually circulate through the microporous balloon 120 and the electrodes 121, 128. Female coupling 135 can be connected to drug administration apparatus. Mechanical switch 136 allows for the activation of individual electrodes in a manner, the manner including selecting any of number, sequence, pattern and position, that is responsive to the judgment of medical or veterinary personnel. The port 131, port 132, female couplings 133, 134, 135 and mechanical switch 136 are all located immediately adjacent to the handset 137 to allow easy operation.

Detailed Description Text - DETX (69):

In a step 503, viewing apparatus coupled to port 132 is used to examine the interior walls of the fallopian **tube,** search for occlusions, evaluate the position of the catheter 110 and **balloon** 120, and determine which areas are targeted for ablation.

Detailed Description Text - DETX (71):

In a step 505, the syringe is used to exert positive pressure and inflate the inflatable, microporous **balloon** 120 with air or liquid. Inflation of the **balloon** 120 serves several purposes. First, in some instances, it is possible that simple inflation of the **balloon** will be sufficient to dilate an occluded region. Inflation of the **balloon** 120 also causes the electrodes 121, 128 to be positioned snugly against the walls of the fallopian **tube**. Moreover, the inflatable microporous **balloon** 120 also helps anchor the catheter in place.

Current US Cross Reference Classification - CCXR (3):

606/192

US-PAT-NO: 6048330

DOCUMENT-IDENTIFIER: US 6048330 A

TITLE: Systems and methods for promoting tissue growth

---------- KWIC ---------

DATE ISSUED - PD (1):
20000411

Brief Summary Text - BSTX (11):
In one aspect, the present invention encompasses devices for delivering fluids under pressure to an interstitial cavity (e.g., the urinary bladder) within a patient. Generally, the devices include an inflatable balloon, a catheter element that couples a source of fluid under pressure into fluid communication with the inflatable balloon, and a **valve** element that is adapted to restrict the flow of the fluid to a select direction of flow and thereby prevent back flow of fluid. The balloon is preferably dimensioned for placement within an interstitial cavity, e.g., the balloon is selected such that the balloon will exert pressure on a tissue wall such that tissue expansion is promoted. The catheter element includes a first lumen for flowing the fluid under pressure into the balloon. The catheter preferably includes at least one drain opening at or near a distal end of the catheter, drainage means (e.g., a body fluid collection element such as a drainage bag) secured to a proximal end of the catheter, and a second catheter lumen in fluid communication with the drain opening and the drainage means, for drainage of a body fluid from the body cavity to the drainage means. Although in a preferred embodiment a single catheter is preferred (which catheter can include a plurality of lumens), it will be understood that the invention also contemplates the use of a plurality of catheter elements (e.g., each catheter having a single lumen) for providing a fluid under pressure and providing a drainage path for a body fluid.

Brief Summary Text - BSTX (14):
The catheter element is adapted for conveying fluid under pressure to the **balloon**. The catheter element can include a silastic catheter **tube** that has a portion dimensionally adapted to fit within an interstitial lumen, such as the ureter. Depending upon the application, the catheter can be a short or long section of, e.g., silastic **tube** or other polymeric tubing, that extends from an injection port and has the **valve** element incorporated therein. The catheter clement is preferably sized to permit insertion and placement of the catheter (and the attached **balloon**), into the urethra and bladder, through a standard cystoscope.

Brief Summary Text - BSTX (16):

In another embodiment, the present invention can be realized as a fluid delivery system that a catheter element for conveying the fluid to the interior of the cavity, a balloon secured to a distal end of the catheter, an injection port element secured to a proximal end of the catheter element that fluidicly couples the pump element with the catheter element, and a **valve** element that restricts the direction of fluid flow thereby preventing a back flow of pressurized fluid escaping through the injection port. The catheter element includes a first lumen for flowing a fluid under pressure into the balloon. The catheter preferably includes at least one drain opening at or near a distal end of the catheter, a body fluid collection element secured to a proximal end of the catheter, and a second lumen in fluid communication with the drain opening and the fluid collection element, for drainage of a body fluid from an interstitial cavity to a drainage device at a proximal end of the catheter. The apparatus can further include a pump element for providing a source of fluid under pressure.

Brief Summary Text - BSTX (19):

The injection port element is adapted for fluidicly coupling the pump element to the catheter element and can be integrally formed with the **valve** that is adapted to prevent pressurized fluid within the catheter from back flowing and escaping through the injection port element. The injection port can have a mounting element that is adapted for removably and replacably coupling in fluid communication to the pump element. The mounting element can be a threaded nipple, a latch or any other coupling that can form a pressure resistant fluid seal. In one embodiment, the injection port element can be an injection port that is adapted for subcutaneous implantation within a patient or for transcutaneous attachment to a patient.

Brief Summary Text - BSTX (22):

The device can additionally include a pressure release element that reduces fluid pressure by releasing fluid from within the balloon or first catheter lumen. The pressure release element can include a **valve** and pressure sensor disposed within the pump element, to measure the fluid pressure of the fluid provided to the first catheter lumen and to deactivate the pumping element in response to a fluid pressure within the catheter when the pressure exceeds a selected maximum pressure or to release fluid from within the catheter by action of the **valve** element.

Brief Summary Text - BSTX (23):

In another aspect of the invention, methods are disclosed for treating volume deficiency disorders of a body structure by expanding, enlarging, or inflating a volumetrically deficient body structure. The methods employ a tissue dilation system that comprises a source of fluid under a select pressure, an inflatable balloon, a catheter element for carrying the fluid under pressure to the balloon, and a **valve** element for restricting said fluid under pressure to a select direction of fluid flow. The method further includes the steps of introducing the inflatable balloon into the volume deficient body structure and introducing fluid into the balloon to dilate a

tissue wall of the body structure to cause tissue expansion (e.g., by promoting tissue growth), such that the volume deficiency disorder is treated, i.e., the volume of the body structure is increased.

Brief Summary Text - BSTX (28):

In another aspect of the present invention, methods are provided for expanding tissue to promote tissue growth. The method includes the step of introducing fluid under a select pressure into a balloon disposed within an interstitial cavity by providing a pump element for providing fluid at a select pressure, fluidicly coupling a catheter element between the pump element and the balloon, providing a **valve** element within the catheter that prevents flow back by restricting the introduction of fluid to a select direction of fluid flow, and sealing fluid-wise the balloon to the catheter element.

Detailed Description Text - DETX (3):

To this end, the present invention encompasses fluid delivery systems that include an inflatable balloon, a catheter element for coupling to a source of fluid under pressure and for delivering the fluid to the balloon, and a **valve** element that restricts the direction of fluid flow thereby preventing back flow of pressurized fluid from escaping through the port.

Detailed Description Text - DETX (4):

FIG. 1 illustrates a system 10 constructed according to the present invention for delivering fluids at a select pressure into a balloon 26 disposed within an interstitial cavity 24A. The system 10 includes a catheter element 12 that has a port element 14 with an optional safety release element 14A, a **valve** element 28, a pump element 16 having a manometer 18, and an exit port 22 in catheter 12.

Detailed Description Text - DETX (6):

In the illustrated embodiment of FIG. 1, the catheter element 12 is a silastic catheter adapted for being subcutaneously inserted within a patient during the tissue expansion process. An exit port 32 extends through the distal end 20 of the catheter 12 to provide a fluid path into the balloon 26. In the illustrated embodiment, the distal end 20 of the catheter element 12 is dimensionally adapted for inserting into the lumen 24A of the a natural body cavity such as the bladder. At the proximal end of the catheter element 12, the catheter is connected to a port element 14 that includes the **valve** element 28. Preferably, the catheter element 12 is coupled to the port element 14 in a pressure resistant fluid tight manner that maintains a seal between the catheter element 12 and the port element 14 when the catheter element 12 is filled with fluid under pressure. The proximal end portion can be a separately manufactured element that couples to a catheter element 12 with a pressure resistant fluid tight seal that maintains a sealed connection between the catheter element 12 and the proximal end element when the catheter element 12 contains fluid under pressure. The catheter clement 12 can be any of the silastic catheter elements that are sufficiently pressure resistant to contain fluid at the pressure level appropriate for the particular application.

Detailed Description Text - DETX (11):

Referring again to FIG. 1, the port element 14 illustrated in FIG. 1 can be an injection port that has a **valve** 28 formed from a septum integrally constructed into the port element 14. The septum **valve** 28 can be an elastic **membrane** of the type commonly used in subcutaneously implanted injection ports and being a self-sealing **membrane** that forms a pressure resistant fluid seal around a needle element such as the hypodermic needle element 16A illustrated in FIG. 1 as penetrating the septum. By providing a septum **valve** 28 that seals about a needle element 16A with sufficient strength to prevent fluid contained under pressure within the catheter element 12 from escaping through the septum wall, the **valve** element 28 restricts fluid under pressure to a select direction of flow as it is introduced through the needle 16A into the catheter element 12, and thereby prevents flow back. In an alternative embodiment, the port element 14 can be a fitting or connector, such as a Luer connector, suitable for coupling to a source of fluid under pressure (e.g., a pump).

Detailed Description Text - DETX (12):

The pump element 16 illustrated in FIG. 1 is a syringe that has a needle element 16A adapted for carrying a fluid, a pressure sensor element 18, a fluid reservoir 36 and a piston element 38. The pressure sensor can be a manometer element 18 that couples in fluid communication to the fluid within the reservoir 36 and can indicate the pressure of the fluid within the reservoir 36 being injected into the catheter element 12, and thereby indicate the pressure of the fluid within the balloon 26. In operation, the piston element 38 is depressed into the fluid reservoir 36 to place the fluid under pressure and to inject the fluid through the hollow needle element 16A that has penetrated through the **valve** element 28. The septum **valve** 28 comprises a thickened portion of, preferably a silicone elastomer material having characteristics which permit repeated, intermittent puncture by a needle 16A for injecting fluid at a select pressure from the fluid reservoir 36. Such a needle 16A is preferably 20 gauge or smaller.

Detailed Description Text - DETX (13):

FIG. 3 illustrates a system 60 that represents an alternative embodiment of the present invention. System 60 includes the port element 14, catheter 12, and balloon 26. The catheter 12 has a first lumen 12A which is in fluid communication with the balloon 26 and with a source of compressed air 40, through **valve** element 44. **Valve** element 44 can be any one-way **valve** adapted for retaining a fluid under pressure within the system, including check valves and the like. The one-way **valve** element illustrated in FIG. 3, fluidicly seals the fluid deliver system to thereby prevent fluid (e.g., compressed air) from escaping from the balloon. The illustrated one-way **valve** 44 is merely one check **valve** that can maintain a closed condition responsive to fluid pressure in order to fluidicly seal a balloon maintaining a fluid under pressure. It should be apparent to one of ordinary skill in the art that other one-way valves, check valves, and other pressure containment elements can be practiced with the present invention without departing from the scope thereof and it is considered to be within the skill of one of ordinary skill in the art to

provide alternative one-way **valve** elements.

Detailed Description Text - DETX (17):
FIG. 3 further illustrates means for delivering and maintaining fluid under pressure within a body cavity 24A. The pumping assembly 40 illustrated in FIG. 3 includes a pressure indicator 18, a motor assembly 52, a connecting lumen 54 that includes a pressure release **valve** 56, and pressure control knob 58.

Detailed Description Text - DETX (18):
The illustrated pumping clement 40 can be any conventional air pumping element for providing a source of air under a select pressure. The pumping element 40 can be a peristaltic pump or any other conventional pumping system. The motor assembly 52 is an electric motor pump that moves air through the fluid delivery lumen 54, past the port 14, through catheter 12 and into the balloon 26. In one embodiment, the pressure indicator gauge 18 measures the pressure of air being pumped into the balloon 26. The fluid pressure can be selectively controlled by an operator, by adjusting the control knob 58 that connects to a control element within the pump assembly 40 that controls the pumping motor 52 to establish a select fluid pressure for the fluid being pumped. The control element receive input from manometer 18 that measures the fluid being forced through the lumen 54 and into the balloon 26. The pump control element can be electrical circuit card assembly having a processing unit, data memory and program memory. The control element can operate in response to a program of processing unit instruction codes, to respond to the measured fluid pressure to maintain the selected pressure level, to deactivate the pump if a maximum pressure limit is reached, or to open the pressure release **valve** 56 if a maximum pressure is exceeded. If desired, a feedback lumen (not shown) can be provided to communicate a pressure in the balloon 26 to manometer 18, to directly measure the pressure in balloon 26.

Detailed Description Text - DETX (25):
A catheter device of the invention was inserted through the urethra of a female human patient (aged about 15 years) suffering from bladder volume insufficiency. The starting bladder volume was about 15 ml. The balloon was then inflated with compressed air over a period of about one hour. Balloon expansion continued until the patient indicated increasing discomfort. Balloon inflation was halted, and the pump was uncoupled; a **valve** maintained the fluid pressure within the balloon catheter system. The patient reported little subsequent discomfort and was not hospitalized (a urine collection bag can collect urine (through drain openings in the catheter) while the catheter remains in position, if desired). The system was then removed. The total bladder volume after the expansion procedure was about 80 ml. Thus, the bladder volume was significantly increased after only a single session of expansion, with minimal patient discomfort and surgical intervention.

Detailed Description Text - DETX (26):
This system can also be used to dilate and expand growth of tissues in other organ systems where tissue shortage is present. Patients with a short gut

syndrome who are born with or acquire a limited amount of gastrointestinal tract, would also be ideal candidates for this technology. Currently, some patients with the short gut syndrome have no therapeutic recourse and die. The system of tissue dilation and expansion could also be used for patients with inadequate lung volume either to congenital or acquired conditions. These patients usually require extracorporeal **membrane** oxygenation (ECMO), which in of itself, carries an 80% mortality. Hydraulic tissue expansion could be performed through the trachea with a similar device into an individual lung organ while the patient is on ECMO. This system could also be utilized to expand individual blood vessels which could later be used for any type of vascular bypass surgery as graft material, such as that needed in aorto-femoral surgery, thereby avoiding the need for artificial materials such as polytetrafluoroethylene (Teflon) grafts, which are associated with various complications. This system could also be used for local tissue expansion, such as for skin or scalp areas, e.g., where additional integument is needed for reconstructive purposes. This system could be further used for bladder augmentation, urethral dilation, ureteropelvic junction obstruction repair, ureterovesical junction obstruction repair, repair of ureteral, urethral, or bowel strictures, or any area in the body where an obstructive process occurs due to strictures, adynamic segments, or lack of tissue or volume. Other organs which can be expanded with the systems and methods of the invention include vagina, uterus, Fallopian tubes, and the like. This system could also be for gastric dilation, expansion of tracheal tissue, esophageal enlargement, intestinal expansion, and any area where dilation or tissue expansion is required.

Claims Text - CLTX (5):
a **valve** element that prevents backflow out of said injection port; and

Claims Text - CLTX (10):
the **valve** element is disposed within the injection port and further comprises a septum adapted to elastically form a seal around a hypodermic needle.

Current US Cross Reference Classification - CCXR (3):
606/192

US-PAT-NO: 5411479

DOCUMENT-IDENTIFIER: US 5411479 A
See image for Certificate of Correction

TITLE: Cancer treatment and catheter for use in treatment

---------- KWIC ---------

DATE ISSUED - PD (1):
19950502

Brief Summary Text - BSTX (36):
"Techniques for perfusion of the liver have been complicated, and represent major abdominal surgery. Our techniques, developed for the experimental animal and applicable to patients, involved isolation of the liver by passing a Foley **balloon** catheter (Bard Urological Division, Murray Hill, N.J.) with a ligated tip through the vena cava from the femoral vein to a point proximal to the hepatic veins. The vena cava was occluded above by the **balloon** that was positioned above the diaphragm and below the hepatic veins by a snare placed above the renal veins (FIG. 7), and the hepatic vein drainage was returned to the pump reservoir through the catheter. The hepatic artery was temporarily clamped, and oxygenated blood, and oxygenated blood from the pump and the chemotherapeutic agents were delivered to the liver through the proximal portal vein. Blood from the distal portal vein and vena cava was returned to the heart through an accessory bypass from the femoral vein to the external jugular vein. We did not persist in our efforts to use hepatic perfusion clinically, but other investigators have separately developed techniques for perfusion of human livers. The approach developed by Aigner and colleagues uses a double-lumen **tube** to collect hepatic venous blood in the outer **tube**, with bypass of the distal caval blood through the inner **tube**. Arterial blood and chemotherapy are

Detailed Description Text - DETX (14):
The double balloon catheter, once properly located in the body, extends through the skin to the outside of the body. It terminates in a Luer fitting and a **valve** cutoff such as a stopcock. The extracorporeal circuit can be separated from the double balloon catheter and reconnected at will. When the balloons are not inflated, blood flow through the IVC is maintained when the balloons are inflated, the blood below the peripheral balloon will find secondary pathways to the heart.

Detailed Description Text - DETX (15):
This convenience may be duplicated on the supply side of the process, where the chemotherapuetic agent is supplied to the arterial side of the liver, via

the hepatic artery, by the percutaneous insertion of a feed catheter to the hepatic artery, leaving the tubular ending of the feed catheter in a plastic reservoir surgically implanted just below the patient's skin and surgically tied therein below the skin. The plastic reservoir contains a resealing **membrane** of a type similar to those used in multi-dose vials that can be percutaneously penetrated from the outside of the body by one or more needles to reinitiate the flow of chemotherapuetic agent to the diseased organ. Illustrative of such devices is Implantofix.RTM. Drug Delivery System, sold by Burron Medical Inc., 824 Twelfth Avenue, Bethlehem, Pa. 18018.

Detailed Description Text - DETX (41):

Hemofiltration is a well defined technology and is characterized in a number of texts. It involves the filtration from the contaminated blood of the antineoplastic agent through **membrane** walls. Details of the process and the apparatus used in effecting the process are described in inter alias Malchesky, **Membrane** Plasma Separation; Critical Issues, Therapeutic Apheresis: A Critical Look, edited by Y. Nose, P. S. Malchesky, and J. W. Smith, ISAO Press, No. 304, pp. 93-101, Cleveland, Ohio U.S.A., 1984; Vassilieff, et al., Plasmapheresis Between a Rotating Truncated Cone and a Microporous Plate, Therapeutic Apheresis: A Critical Look, edited by Y. Nose, P. S. Malchesky, and J. W. Smith, ISAO Press, No. 304, pp. 102-114, Cleveland, Ohio U.S.A., 1984; Raft, et al., Influence of Geometric Parameters on Filtration Flux in Plasma Filters, Therapeutic Apheresis: A Critical Look, edited by Y. Nose, P. S. Malchesky, and J. W. Smith, ISAO Press, No. 304, pp. 115-121, Cleveland, Ohio U.S.A., 1984; Koga, et al., Investigation of the Clinical Properties of Various Filters for Double and Triple Filtration Plamapheresis, Therapeutic Apheresis: A Critical Look, edited by Y. Nose, P. S. Malchesky, and J. W. Smith, ISAO Press, No. 304, pp. 171-175, Cleveland, Ohio. U.S.A., 1984; Tani, et al., New Anticancer Treatment by Hemoperfusion with Endotoxin Immobilized Fiber, Therapeutic Apheresis: A Critical Look, edited by Y. Nose, P. S. Malchesky, and J. W. Smith, ISAO Press, No. 304, pp. 202-207, Cleveland, Ohio U.S.A., 1984; Fabbri, et al., Twelve-Hour Hemoperfusion on Activated Coated Charcoal with Heparin and Prostacyclin in Healthy Rabbits, Therapeutic Apheresis: A Critical Look, edited by Y. Nose, P. S. Malchesky, and J. W. Smith, ISAO Press, No. 304, pp. 208-216, Cleveland, Ohio U.S.A., 1984; and Gelland, et al., Extracorporeal Induction of In Vivo Suppressor Cell Predominance by Plasmaleukapherisis: An Alternative to Cyclosporin in Renal Transplantation, Therapeutic Apheresis: A Critical Look, edited by Y. Nose, P. S. Malchesky, and J. W. Smith, ISAO Press, No. 304, pp. 217-240, Cleveland, Ohio U.S.A., 1984. A detailed review of the subject of hemofiltration can be found in Henne, et al., **Membrane** Technology for Plasmapheresis, Plasma Separation and Plasma Fractionation, pp. 164-179 (Karger, Basel 1983). The disclosure of these references as they relate to hemofiltration especially in extracorporeal circuits are incorporated herein by reference.

Detailed Description Text - DETX (53):

With respect to FIG. 1, there is shown the featured components of the apparatus assembly of the invention used to practice the process of the invention in relation to a human body 2. Liver 3 is supplied with cancer therapy drugs from syringe 4 through tubing leading to catheter 6 located in

hepatic artery 5. The hepatic venous blood containing anti-cancer concentrations of chemotherapuetic agent is passed via the hepatic veins 7 to the double **balloon** catheter located in IVC 1. The balloons of the double **balloon** catheter are positioned central and peripheral of the hepatic veins 7. The contaminated blood is passed through the double **balloon** catheter to tubing 17 to a point exterior to the body 2, thence to a pump 21 such as a Bio Medicus BP-50 Bio-Pump having a priming volume of 48 ml, containing two rotator cones and providing a maximum flow rate of 5 liters per minute. Pump 21 moves the blood through the extracorporeal circuit at relatively constant low pressure, the object being to avoid raising or lowering the fluid pressure of the total circuit ranging from the hepatic veins through the return to the body. The contaminated blood is transported through tubing 41 into detoxification zone 43, which in this case is a hemoperfusion cartridge containing activated carbon. Suitable cartridge systems are obtainable from Clark Research and Development, Inc., New Orleans, La. 70121 and from Gambro Dialysatoren KG, d-7450 Hechingen, Federal Republic of Germany AUT 224 (sold under the trademark of ADSORBA.RTM.). The detoxified blood is passed through **tube** 44 to effect infusion through the subclavian vein (not shown) by standard procedures in the art.

Detailed Description Text - DETX (54):

With respect to FIG. 2, there is shown the relationship of inferior vena cava I to liver 3, hepatic veins 7 and portal veins 5. The hepatic artery is not shown in the drawing. Double **balloon** catheter 9 comprises central **balloon** 11 and peripheral **balloon** 12, each in juxtaposition to cylindrical fenestration zone 8. Zone 8 contains fenestrations 13 sufficient in total area to allow the complete removal of the hepatic venous flow into the catheter 9. The hollow interior (main lumen) of catheter 9 is of sufficient size to completely remove the blood from the hepatic veins without elevating hepatic back pressure. Catheter 9 is provided with channel 15 that is used to inject fluid into the balloons 11 and 12 for inflation or to withdraw fluids for deflation. The venous flow is passed through catheter 9 into openly connected **tube** 17. **Tube** 17 may be interrupted by a pressure monitor the same as assembly A, discussed below, that is later provided in the extracorporeal circuit. **Tube** 17 may connect directly with pump 21 or to Y-fitting 19, as shown. Also connected to Y-fitting 19 is ancillary feed system B comprising **tube** 23, Y-fitting 25, and multiple IV spikes 29 and 33 each connected to tubes 30 and 31 respectively, and each is provided with a clamp, 27 and 28, respectively. These lines can be used for the introduction of medications as required.

Detailed Description Text - DETX (55):

Pump 21 is a smooth rotator pump design and a particularly desirable pump is a Bio Medicus BP-50 Bio-Pump having a priming volume of 48 ml, containing two rotator cones and providing a maximum flow rate of 5 liters per minute. The contaminated blood is gently pushed between the smooth rotators 37 in zones 35 and issued from the pump through port 39 into tube 41. Tube 41 is connected to cartridge or canister 43 containing a meshed sack of activated carbon particles coated with an acrylic resin containing heparin, see Clark, supra. The outflow from cartridge 43 is fed to tube 45 and then to tube 47 that is connected to pressure monitoring assembly A. Pressure monitoring assembly A comprises a

pressure monitor gauge 55 connected to fluid **membrane** vessel 53 that contains a thin **membrane** that separates the gauge 55 from the blood in vessel 53 and responds to the fluid pressure of the blood in vessel 53. That response is read by the gauge. Vessel 53 is connected to tubing 57, that is connected to stopcock 52. Stopcock 52 is connected to flexible tubing 59 that in turn is connected to stopcock 51, the latter secured in fitting 49.

Claims Text - CLTX (6):

6. A catheter adapted for percutaneous insertion into a vein or artery, comprising: a plastic **tube** having a cranial end and a caudal end and defining a main lumen for outflowing blood, caudal and cranial balloons, fixedly spaced apart about said plastic **tube** and bonded thereto for inflation thereabout, one being contiguous to the cranial end of said plastic **tube,** and said balloons, when inflated, having a size sufficient to block the flow of blood in a vein or artery into which said catheter is designed to be inserted; fenestrations in said plastic **tube** between said balloons to said main lumen, a second and third lumina within said plastic **tube,** said second lumina connecting to the **balloon** at said caudal end and said third lumina connecting to the cranial of **balloon** at the cranial end for effecting inflation or deflation of said balloons, the cranial end of said plastic **tube** is adapted to carry a smaller return catheter and said cranial end tapers to fit about said return catheter.

Claims Text - CLTX (9):

9. An apparatus of claim 1 wherein said caudal end extends through the skin of the patient to the outside of the body and terminates in a Luer fitting and a shut-off **valve**.

Claims Text - CLTX (18):

13. The kit of claim 11 wherein said second catheter fits within said plastic **tube** and said cranial end tapers to fit thereabout such that the treated blood is returned past the cranial **balloon** and said kit includes arterial injection means for introducing said treating agent into an artery leading to said body organ.

Current US Cross Reference Classification - CCXR (4):

606/192